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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,618	12/21/2001	Bernhard Clasbrummel	P01,0578	4762

26574 7590 10/01/2003

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EXAMINER
ORTIZ RODRIGUEZ, CARLOS R

ART UNIT	PAPER NUMBER
2125	10

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,618	CLASBRUMMEL ET AL.	
	Examiner	Art Unit	
	Carlos Ortiz-Rodriguez	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over White U.S Patent No. 4,436,684 in view of Kienzle, III et al. U.S. Patent No. 6,285,902.

Regarding claim 1, White et al. discloses a method for preparing an anatomical implant (see col. 2 lines 13-14 and col. 1 lines 7-9), comprising the steps of: in a medical intervention procedure, intra-operatively generating a three-dimensional dataset (see col. 1 lines 10-12) of body tissue (see col. 1 lines 46-50 also see col. 24 lines 44-46) of a subject exhibiting a fault to be corrected by an implant (see col. 1 lines 59-65) from a series of two dimensional projections of the body tissue obtained from respectively different projection directions(see col 2 lines 63-68 and col 24-28); and in a medical intervention procedure, intra-operatively preparing said implant adapted for introduction into said subject from said three-dimensional dataset (see col 2 lines 14-22).

But, White et al. fails to clearly disclose a C-arm. However, Kienzle, III et al. discloses a movable C-arm x-ray apparatus, by moving an x-ray source and a radiation receiver on a C-arm around said subject (see fig 1 and fig 7 also see col 8 lines 14-23).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms are frequently utilized in the art, especially for CT (computed tomography) scan as suggested by Kienzle, III et al. CT scan is the process of using digital processing to generate a three-dimensional image of the internal of an object from a series of two-dimensional x-ray images. The individual x-ray axial slice images are taken using an x-ray tube that rotates around the object taking many scans of the object.

Regarding claim 2, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising acquiring a three-dimensional dataset which represents a bone structure of said subject(see col 9 lines 63-65 and col 10 lines 50-54 and also see fig.10).

Regarding claim 3, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising intra-operatively

preparing said implant with an automated device which is supplied with said three-dimensional dataset (see col 2 lines 14-22 also see fig 8a).

Regarding claim 4, White discloses an apparatus for preparing an anatomical implant (see col 2 lines 13-14 and col 1 lines 7-9), an apparatus, during a medical intervention procedure, intra-operatively generating a three-dimensional dataset (see col 1 lines 10-12) of body tissue (see col 1 lines 46-50 also see col 24 lines 44-46) of a subject exhibiting a fault, to be corrected with an implant (see col 1 lines 59-65), by obtaining a series of two-dimensional projections of the body tissue from respectively different projection directions(see col 2 lines 63-68 and col 24-28) by moving a x-ray source and said radiation detector thereon, around the body tissue(see col 8 lines 53-58); and an implant-producing device which intra-operatively produces said implant from said three-dimensional dataset, during a medical intervention procedure(see col 2 lines 14-22 also see fig 8a).

But, White fails to clearly disclose a C-arm. However, Kienzle, III et al discloses a C-arm C-arm comprising a x-ray apparatus having an x-ray source and a radiation receiver mounted thereon (see Kienzle fig 1 and fig 7 also see col 8 lines 14-23), said C-arm x-ray apparatus intra-operatively generating a three-dimensional dataset (see col 1 lines 10-12).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms are frequently utilized in the art, especially for CT (computed tomography) scan as suggested by Kienzle, III et al. CT scan is the process of using digital processing to generate a three-dimensional image of the internal of an object from a series of two-dimensional x-ray images. The individual x-ray axial slice images are taken using an x-ray tube that rotates around the object taking many scans as the object.

Regarding claim 5, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said dataset represents a bone structure, and wherein said implant is adapted to replace said bone structure (see col.3 lines 24-31 also see col.24 lines 40-43).

Regarding claim 6, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said implant-preparing device is an automated device which is supplied with said three-dimensional dataset and automatically prepares said implant therefrom (see col 2 lines 14-22 col. 9 lines 29-40 and also see fig 8a).

3. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over White U.S Patent No. 4,436,684 and Kienzle, III et al. U.S. Patent No. 6,285,902 in view of Ergun et al. U.S Patent No. 6,007,243 .

Regarding claims 7-10, White in combination with Kienzle, III et al. discloses all the limitations of base claims 1 and 4. But, White in combination with Kienzle, III et al. fail to clearly specify rotating the C-arm approximately 190°.

However, Ergun et al. discloses the C-arm having an angulation axis and an orbital axis and rotating approximately 190° around the angulation/orbital axis (see col 5 lines 58-67 and col 6 lines 1-21 and fig 1, 2,3).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and Kienzle, III et al. and modifying it with the invention disclosed by Ergun et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms with the ability to move or rotate to desired positions are commonly used in the medical area in order to provide flexibility in positioning the C-arm as disclosed by Ergun et al.

Response to Arguments

Applicant's arguments filed 7/14/03 have been fully considered but they are not persuasive. White discloses obtaining three-dimensional dataset during a medical intervention procedure and producing a medical implant from the 3D image dataset during the medical intervention(see abstract and col 1 line 41). Kienzle, III discloses producing three dimensional datasets(see col 4 lines 49-50) similar to the acknowledgement made in the remarks submitted in reply to the first office action mailed. The acknowledgment stated that C-arm x-ray systems have been used in, and are known to be suitable for use in, an operating room environment in order to generate a 3D dataset to produce an image for monitoring the progress of a medical intervention procedure. This statement seems to disclose that it is well known in the art to generate 3D datasets and preparing images/implants intra-operatively in operating room environment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with respect to method and apparatus for preparing an anatomical implant:

a. U.S. Pat. No. 5,287,274 to Saint Felix et al., which discloses method for acquisition of radiological data in multiple orthogonal orientations.

b. U.S. Pat. No. 6,050,724 to Schmitz et al., which discloses a method of and device for position detection in X-ray imaging.

c. U.S. Pat. No. 6,155,713 to Watanabe, which discloses x-ray diagnostic apparatus having an x-ray generating portion and an x-ray generating portion.

d. U.S. Pat. No. 6,256,374 to Tomasetti, which discloses miniature c-arm apparatus.

e. U.S. Pat. No. 6,496,558 to Graumann, which discloses x-ray device and medical workplace for diagnostics and surgical interventions in the head and/or jaw of a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Ortiz-Rodriguez whose telephone number is (703) 305-8009. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P. Picard can be reached on (703) 308-0538. The central fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Carlos Ortiz-Rodriguez
Patent Examiner
Art Unit 2125

cror

September 25, 2003

LEO PICARD
SUPERVISORY PATENT EXAMINER
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